

SPL ER/DL Team

Mar 02, 2011

Minutes

Teleconference information:

USA Toll-Free 866-213-2145

Access code: 273 8216

Chair for this meeting: Pat Cowall

1. Follow up on the discussion from last week. Someone mentioned that a reference will appear on drugs@fda when an SPL is submitted with a future marketing date (ex. PLAIR). What is meant by reference? What shows up? I understand the label will not appear, but for an unapproved drug product, what would the reference be? (Beth Macioci)
 - a. At drugs@fda, major supplements are posted.
 - b. At the FDA label web site, the label will not show up unless the product is approved.
 - c. Does a product name show up?
 - d. New site has just shown up and we still don't know what is in there
 - e. GSK doesn't do PLAIR.
 - f. NCEs still have uncertainty about ingredients, etc. The advantage to drug listing early will be to test out errors.
 - g. Has anyone sent anything in the last 2 weeks that failed. Yes. You asked for the manual override. And then they didn't up Unapproved drug got on the daily med....because the future market start date (June from Roche).
 - h.
2. When was the most recent PLAIR submitted ? Was it drug listed? (Beth Macioci)
 - a. When the option came out NOT to drug list the PLAIR, Jean has not drug listed after that.
 - b. They received approval to import (with a PLAIR)...without drug listing.
 - c. Jean will follow up within her company, and will send us her recent experience
 - d. Is there any benefit to drug listing prior to approval, with a PLAIR.
 - e.
3. Is anyone using the SPL as the primary document and then rendering the xml to word. (Jean Kirkeleit Davis)
 - a. Not yet.
 - b. Ruth at Teva does it this way. i4i. Renders
4. Question sent to Pat: We recently started receiving a 2nd acknowledgement to remove the confidentiality code from our inactive ingredients section. Is this a recent update? Just curious if you have seen this one.
 - a. No.
 - b. Tanya from Perrigo. FDA is now saying that they want an active on everything. Therefore if you mark everything as confidential, then public can't see it.
 - c. If you only have a few of the inactives listed, it would fail validation. They want information available.
 - d. The validation rules haven't changed, this is a manual check. ie a person is looking at the file.
 - e. Underlying concept is by having the coding, it allow people elsewhere to connect to the data – big benefit for downstream users.

- f. If ingredients are listed on the box, why shouldn't they be in the SPL?
 - g. Where is this referenced in guidance? This goes back to interpretation of the law/regulations. The data is also visible. Thus the enforcement happens more easily.
 - h. This was a topic that was scheduled to be brought up at an OTC meeting or at a technical team meeting.
- 5. Printing to PDF -- Update from the Technical Lead Team (Pat and Terry)
 - a. FDA doesn't want to be responsible for maintaining a file that they don't use and maintain. They got a file from somewhere else.
 - b. They will not provide a pdf renderer.
 - c. Pat to talk to Gary Saner – Reed Technology.
- 6. Teleconference discussion Drug Listing - March 30, 1 to 2:30
 - a.
- 7. Walk ins
 - a. Paper certificates – What happens when foreign companies want a printed certificate. They
 - b. PDP on OTC What is included in the principal display panel of your label.
 - c.

Upcoming Meetings being planned:

- Discussion with CMS: Jessica
- Discussion with First DataBank: Michelle
- Discussion with DRLS: Pat – March 30